REMARKS

Claims 1 and 3-23 are currently pending in the application. Claims 24-27 and 32 are canceled without prejudice and will be pursued in a continuation application. Claims 1, 6 and 18 are amended. Claim 2 has been cancelled. The amendments to claims 6 and 18 are made to correct obvious typographical errors that would not have prevented one of ordinary skill from understanding the scope of the claims. Claim 1 has been amended to incorporate the subject matter of dependent claim 2. No new matter is added.

THE INVENTION

Applicant's invention is directed to a tissue implant comprising therapeutic material associated with a scaffold structure. The scaffold can include an interior defining a chamber with at least one opening, where the therapeutic material is associated with the interior of the scaffold. Alternatively, the therapeutic material can be on the exterior of the scaffold, or the scaffold structure can be porous, and the material can be associated within the pores.

The implant and therapeutic material should be securely anchored in the tissue to prevent migration, and the device "provides a scaffold structure to hold the moving tissue back so as not to squeeze out the implanted therapeutic material." (page 6, lines 10-22).

CITED ART

Gambale *et al.* (U.S. Pat. No. 6,432,126; "Gambale")

Gambale discloses implants and delivery systems for promoting angiogenesis in ischemic tissue. The implants can be implanted into the myocardium.

The implants are configured to be flexible so that they compress and expand with movement of the surrounding tissue. Blood flows in and out of the implant as it is compressed and expands. The flow of blood into the implant and pooling in the implant causes formation of thromboses and fibrin growth. This leads to angiogenesis in the surrounding tissue.

The implants can also contain an angiogenic substance or a thrombus, which can be preloaded or injected into the device after implantation.

Cafferata (U.S. Pat. No. 6,689,121; "Cafferata")

Cafferata discloses a system and method for implanting pellets into myocardial tissue for treatment of disease. The pellets serve as depots, delivering medication to the area in which they are implanted. The medication can be a pharmaceutical, a viral or non-viral vector, cells, plasmid-liposome complexes, DNA delivery complexes, oligonucleotides, etc.

Slepian *et al.* (U.S. Pat. No. 5,575,815; "Slepian")

Slepian discloses a method for providing a synthetic barrier made of biocompatible polymeric materials *in vivo*. The material is applied in a fluid state to a tissue or a cellular surface (such as the interior of the blood vessel). It adheres to the tissue surface, and is then converted to a non-fluid state.

CLAIM REJECTIONS

Claim Rejections Under 35 U.S.C. § 102(e)

Claims 1-6, 13, 17-20, 22-27 and 32 were rejected under 35 U.S.C. § 102(e) as anticipated by Gambale. The Office Action states that this reference (especially Figures 1-9) discloses the invention as claimed, namely, a scaffold structure that is implantable in tissue, with an interior chamber with at least one opening, and which is associated with a therapeutic material.

Applicant respectfully disagrees with the characterization of this reference. All of the implants disclosed in Gambale are flexible, and compress and expand with the movement of the surrounding tissue. There is no suggestion that the implants are rigid in any way, or that they should not flex with tissue movement. In contrast, Applicant's claims disclose scaffold structures associated with therapeutic material, not implants which are configured to flex with tissue movement. Rather, the specification states that

> The device and associated material should be securely anchored in the tissue to prevent migration from the tissue. Therapeutic material such as tissue, cells or cell material may tend to migrate when placed in active muscle tissue such as the myocardium. Cyclic contraction and relaxation of surrounding tissue can serve to push the material out of the muscle. *The implant device*

> *provides a scaffold structure to hold the moving tissue back so as not to squeeze out the implanted therapeutic material.*

(page 6, lines 10-16, emphasis added).

In contrast, Gambale makes clear that the device is intended to be compressed as the surrounding tissue contracts, and then expand when the surrounding tissue relaxes. This "cyclical compression and expansion of the implant in concert with the motion of the surrounding tissue creates a pumping action, drawing blood into the implant interior when expanded, then expelling the blood when the implant is compressed." (col. 3, lines 8-12). The cyclic pumping also serves to distribute angiogenic substances associated with the device. This is discussed at col. 3, lines 49-53 ("The blood flow into and interacting with the interior of the device will serve to distribute the substance through the surrounding tissue area because blood entering the device mixes with and then carries away the substance as it leaves the device."), col. 8, lines 17-22 ("The greater volume change provide by the flexible capsule implant between its compressed configuration and uncompressed configuration, provides substantial pumping action, making this embodiment particularly well suited for pumping a preloaded angiogenic substance into the surrounding tissue."), and col. 10, line 65 to col. 11, line 2 ("Compression of the flexible tube as shown in FIG. 6B causes blood flow 20 along with angiogenic substances to be ejected outward through opening 70 and 72 into the surrounding tissue 4.").

Gambale therefore fails to disclose or suggest an implant comprising a scaffold structure, as required by the claims. Applicant respectfully requests that the rejection on this basis be reconsidered and withdrawn.

Claim Rejections Under 35 U.S.C. § 103

Claims 7-11, 16 and 21 were also rejected as obvious in view of Gambale and Cafferata. The office action states that Cafferata teaches that the therapeutic material can be precursor cells, stem cells, cardiomyocytes, DNA and skeletal myoblasts.

As stated above, Gambale teaches implants which are flexible and are configured to compress and expand with the movement of the surrounding tissue. Gambale does not teach implants which include a scaffold. Cafferata also fails to disclose such implants. Where neither reference discloses such a device, their combination cannot render the device obvious.

Furthermore, there is no motivation to combine the two references, and instead, one of ordinary skill would likely be taught away from the combination. As discussed in the present specification, "[t]herapeutic material such as tissue, cells or cell material may tend to migrate when placed in active muscle tissue such as the myocardium. Cyclic contraction and relaxation of surrounding tissue can serve to push the material out of the muscle." Combining the teachings of Gambale and Cafferata would not produce an implant that included a scaffold, but instead would produce an implant into which are placed cells as a therapeutic material, and is compressed and expanded in concert with the movement of the surrounding tissue, . As the implant is compressed by the surrounding tissue, the liquid therapeutic material is squeezed out of the implant. As the tissue relaxes, some of the material would likely be pulled back into the implant, but the liquid therapeutic material would be unlikely to remain in the area for very long.

The combination of Gambale and Cafferata therefore produces an implant with precisely the problems that the present application solves. The combination of these references therefore cannot render obvious applicant's claims, and it is respectfully requested that the rejection on this basis be reconsidered and withdrawn.

Claims 12 and 15 were also rejected as obvious in view of Gambale and Slepian. The office action states that Slepian teaches local polymeric drug therapy and drug adhesives, and that it would have been obvious to associate the therapeutic material with the implant by an adhesive, or to maintain the material in gel form so that it adhered to the implant.

As stated above, Gambale teaches implants which are flexible and are configured to compress and expand with the movement of the surrounding tissue. Gambale does not teach implants which include a scaffold. Slepian also fails to disclose such implants. Where neither reference discloses such a device, their combination cannot render the device obvious.

Applicant therefore respectfully requests that the rejection on this basis be reconsidered and withdrawn.

Double Patenting

Claims 1-27 and 32 were also rejected under the judicially created doctrine of obviousness-type double patenting, in view of claims 1-8 of U.S. Pat. No. 6,719,805. The office

action asserts that it would be obvious to one of ordinary skill in the art that the present claims are a broader re-wording of the subject matter of the '805 patent.

The present application is a divisional application of U.S. App. No. 09/328,808, which issued as U.S. Pat. No. 6,719,805. During prosecution of the parent application, the claims were restricted into two groups, Group I (claims 1-23) and Group II (claims 24-33). The current claims therefore represent the claims of Group I, and a double patenting rejection in view of the parent patent is therefore inappropriate under 35 U.S.C. § 121.

Applicant respectfully requests that the double patenting rejection be withdrawn.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721.

Respectfully submitted,

Joyce C. Hersh
Reg. No. 42,890
Attorney for Applicant
KIRKPATRICK & LOCKHART
NICHOLSON GRAHAM LLP
75 State Street
Boston, MA 02109-1808
Tel: 617-261-3100
Fax: 617-261-3175

Date: February 14, 2005